UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

TRICEUTICAL, INC., a corporation, and Liqun Zhang, an individual,

Defendants.

**COMPLAINT FOR PERMANENT INJUNCTION**

CIVIL ACTION NO.

CV-14 3683

WEXLER, J

LINDSAY, M

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

INTRODUCTION

1. This action is brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the equitable authority of this Court, to enjoin and restrain Triceutical, Inc., a corporation ("Triceutical"), and Liqun Zhang, an individual (collectively, "Defendants"), from violating:

a. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

b. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

## JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

## DEFENDANTS

4. Defendant Triceutical is a New York corporation with its principal place of business at 164 Milbar Boulevard, Farmingdale, New York 11735 (the "facility"), within the jurisdiction of this Court.

5. Individual Liqun Zhang is Triceutical's President.

6. Defendant Zhang is responsible for Triceutical's business operations, including employee training, regulatory affairs, formulations, and manufacturing operations. Defendant Zhang has the duty to prevent, detect, and correct violations of the Act and the authority to hire and fire employees. Defendant Zhang performs his duties at the facility, within the jurisdiction of this Court.

7. Defendants have been, and are now engaged in, manufacturing, preparing, packing, repackaging, labeling, holding, and distributing "dietary supplements" within the meaning of 21 U.S.C. § 321(ff). Such products include, but are not limited to, Children's Growth Formula, Hyaluronic Acid, Joint Optima, Premium Protein III, and Premium Protein III for Kids.

8. Defendants regularly manufacture dietary supplements using components, such as magnesium sulfate, that they receive from outside New York. Defendants also introduce or

deliver for introduction into interstate commerce, such as to Pennsylvania, finished dietary supplements.

DEFENDANTS ADULTERATE THEIR DIETARY SUPPLEMENTS

9. The Act requires manufacturers of dietary supplements to operate in compliance with current good manufacturing practice for dietary supplements ("cGMP"). 21 U.S.C. § 342(g)(1). Manufacturing according to dietary supplement cGMP means that the manufacturing process incorporates a set of controls in the design and production processes to assure a finished product of acceptable, predictable, and reliable quality. Dietary supplements not manufactured, prepared, packed, or held in conformance with cGMP requirements are deemed to be adulterated. 21 U.S.C. § 342(g)(1). The dietary supplement cGMP regulations are set forth at 21 C.F.R. Part 111.

10. The United States Food and Drug Administration ("FDA") inspected Defendants' facility between May 9 and 24, 2013. This inspection established that the dietary supplements that Defendants manufacture, prepare, pack, repack, label, hold, and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not comply with dietary supplement cGMP regulations.

11. During the May 2013 inspection, the FDA investigator documented numerous deviations from cGMP. These deviations include, but are not limited to, the following:

a. Defendants failed to conduct at least one appropriate test or examination to verify the identity of a component that is a dietary ingredient before using such component, in violation of 21 C.F.R. § 111.75(a)(1)(i);

b. Defendants failed to qualify the supplier of a component received by establishing the reliability of the supplier's certificate of analysis, through confirmation of the results of the supplier's tests or examinations, in violation of 21 C.F.R. § 111.75(a)(2)(ii)(A).

c. Defendants failed to verify that their finished batches of dietary supplements met product specifications for identity, purity, strength, and composition, in violation of 21 C.F.R. § 111.75(c);

d. Defendants failed to prepare and follow a written master manufacturing record for each unique formulation of dietary supplement that Defendants manufactured in violation of 21 C.F.R. § 111.205;

e. Defendants failed to prepare an adequate batch production record that includes complete information relating to the production and control of each batch, in violation of 21 C.F.R. § 111.255 (b) and 21 C.F.R. § 111.260; and

f. Defendants failed to design or select manufacturing processes to ensure that product specifications were consistently met, in violation of 21 C.R.F. § 111.355.

12. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

13. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such

articles are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS' HISTORY OF VIOLATIONS

14. Defendants are well aware, and have acknowledged, that their operations deviate from the cGMP regulations and that their failure to cease their violative conduct and implement corrections could lead to regulatory action.

15. FDA previously inspected Defendants' facility between May 16 and 29, 2012 and February 6 through 8, 2012. During both inspections, FDA inspectors observed significant violations of the Act and cGMP regulations. During one or both of these previous inspections, FDA investigators found some of the same and/or similar violations as those observed during the May 2013 inspection of the facility, including, but not limited to, violations involving: failure to conduct identity testing of dietary ingredients, 21 C.F.R. § 111.75(a)(1)(i); failure to test finished product to confirm established specifications are being met, 21 C.F.R. § 111.75(c); and failure to prepare and follow a written master manufacturing record for each unique formulation of dietary supplement Defendants manufactured, 21 C.F.R. § 111.205.

16. At the conclusion of the May 2012 and February 2012 inspections, FDA investigators issued to Defendant Zhang a Form FDA-483, List of Inspectional Observations ("Form FDA-483"), detailing Defendants' numerous deviations of the Act and cGMP requirements, and discussed the documented observations with him.

17. Defendants submitted a written response dated March 2, 2012, to the Form FDA-483, issued at the close of the February 2012 inspection. In the written response, Defendants

acknowledged their violative conduct and promised to implement corrections. Many of these corrective actions were not implemented.

18. On November 8, 2012, FDA issued a Warning Letter to Defendant Zhang, informing him that the significant cGMP violations that FDA documented during the May 2012 inspection rendered Defendants' dietary supplements adulterated under the Act. The Warning Letter emphasized the serious nature of the violations and further cautioned Defendants that their failure to correct the violations promptly, and prevent future violations, could lead to additional regulatory action, including an injunction of their operations.

19. Defendants did not respond to the Warning Letter. The FDA investigator found the same or similar violations during a May 2013 inspection.

20. Based on their repeated course of conduct, Defendants, unless restrained by order of this Court, will continue to violate 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, cease manufacturing, preparing, packing, repackaging, labeling, holding, and/or distributing dietary supplements at or from the facility or at or from any other location(s) at which Defendants manufacture, prepare, pack, repackage, label, hold, and/or distribute dietary supplements, now or in the future, unless and until Defendants bring their manufacturing, preparing, packing, repackaging, labeling, holding, and/or distributing operations into compliance with the Act and cGMP;

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them, be permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

B. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the manufacturing, preparing, packing, repackaging, labeling, holding, and distributing of all of Defendants' products to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated this 11th day of June, 2014.

Respectfully submitted,

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